# Congress of the United States
## House of Representatives
### Washington, D.C. 20515

January 8, 2009

The Honorable Carlos M. Gutierrez
Secretary
U.S. Department of Commerce
Fourteenth Street and Constitution Avenue, N.W.
Washington, D.C. 20230

The Honorable Condoleeza Rice
Secretary
U.S. Department of State
2201 C Street, N.W.
Washington, D.C. 20520

The Honorable Michael Leavitt
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

The Honorable Michael Chertoff
Secretary
U.S. Department of Homeland Security
3801 Nebraska Avneue, N.W.
Washington, D.C. 20395

Dear Secretaries Gutierrez, Rice, Leavitt, and Chertoff:

I am writing to inquire about the extent to which your departments coordinate with respect to the administration of U.S. laws dealing with potential bioterrorism agents. In particular, I would like to know your respective answers to the following question: What regulatory requirements or prohibitions exist for a non-U.S. company doing research and/or clinical trials in a country that is on the U.S. list of states that sponsor terrorism on a product derived from a substance that is on the U.S. list of select agents and toxins?

My question is based on a pending new drug application by Ipsen Limited for Dysport, one of several commercially-produced substances that contain neurotoxic proteins derived from the select agent bacterium Clostridium botulinum. My understanding is that the sponsor, Ipsen

Limited, is not only doing testing and clinical trials of Dysport in the Islamic Republic of Iran, but has also apparently made the drug available to Iranian researchers for their own research.

As part of its responsibilities for new drug approvals under the Federal Food, Drug and Cosmetic Act (FFDCA), the U.S. Food and Drug Administration (FDA) does not currently consider any national security concerns associated with the drug or its sponsor, use of illegal experiments, mishandling of select agents, or transactions with terrorist entities or state sponsors of terrorism.

I would note, however, that your respective departments are responsible for regulating dangerous agents such as dual-use technologies and access to these agents through a variety of regulatory mechanisms including International Traffic in Arms Regulations (ITAR), Export Administration Regulations (EAR), the Select Agents and Toxins (SAT) regulations, and import regulations.

Further, the Congress has tasked you with these responsibilities because we do not believe that other countries have adequate regulatory systems in place to ensure biosafety and biosecurity in areas such as chain of custody, oversight, export, and access to deadly pathogens and toxins. As I and other members of this Committee continue to evaluate the adequacy of the FFDCA and other laws in these areas, we want to ensure that we have a full understanding of your respective departments' regulatory regimes.

I would appreciate your response to this question by January 20, 2009. If you have any questions, please contact Ryan Long with my Committee staff at (202) 225-3641.

Sincerely,

Joe Barton

Joe Barton
Ranking Member
Committee on Energy and Commerce